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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002953460 for a patent by DENNIS JAMES BANNISTER as filed on 20 December 2002.

WITNESS my hand this
Sixteenth day of January 2004

J. Billingsley

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
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P/00/009 28/5/91
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AUSTRALIA

Patents Act 1990

Original

PROVISIONAL SPECIFICATION

Invention Title: **DENTAL FORMULATION**

The invention is described in the following statement:

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DENTAL FORMULATION

FIELD OF THE INVENTION

This invention relates to formulations which can be used for reducing sensitivity or pain in the oral cavity, especially dental sensitivity or pain.

BACKGROUND OF THE INVENTION

Formulations which have been used for treating or preventing sensitivity in the oral cavity have comprised compounds that interact with proteins of the tooth structure and block the ends of the dentinal tubules, or which act as antimicrobial agents. Some examples of such prior art compounds are – benzalkonium chloride in hydroxy ethylmethacrylate, chlorhexidine, glutaraldehyde, and potassium oxalate.

Prior art formulations comprising such active compounds have the disadvantage that they are short lived in effectiveness, and can cause irritation of the soft tissues, such as the gum line. Some active compounds, such as glutaraldehyde, can burn the skin or eyes.

The formulation of the present invention has the advantage that it has long term effectiveness and causes minimal irritation (if any at all) to the tissues of the oral cavity. In addition it is easy to apply and is immediately effective.

SUMMARY OF THE INVENTION

According to a broad form of the invention there is provided a formulation for reducing sensitivity or pain in the oral cavity, comprising at least one desensitising polymer which has been cured by light.

There is also provided according to the invention a formulation for reducing sensitivity or pain in the oral cavity, comprising at least one polymer, characterised in that said polymer has been cured by light.

The polymer in the formulation of the invention is formed from (1) at least one multifunctional polymer or (2) at least one multifunctional polymer and at least one monomer or (3) more than one monomer. A light sensitive polymerisation initiator is mixed with the multifunctional polymer(s) and/or monomer (s) to form a polymer premix. This premix is then applied to the oral cavity, typically to the surface of a painful or sensitive tooth, or to exposed dentine. Light in the wavelength range 300 to 650nm is then directed onto the area to which the premix has been applied, which causes polymerisation and

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thereby forms the desensitising polymer. The use of light for curing formulations which desensitise teeth has not been described in the prior art.

The invention is therefore further directed to a polymer premix used to reduce sensitivity or pain in the oral cavity, comprising at least one multifunctional polymer and/or at least one monomer, together with a light sensitive polymerisation initiator.

The invention is also directed to a polymer premix used to reduce sensitivity or pain in the oral cavity comprising at least one multifunctional polymer and/or at least one monomer, characterised in that the premix also comprises a light sensitive polymerisation initiator.

It is postulated that the polymer premix, which is typically a liquid, penetrates and fills the exposed dentinal tubules. Light is then applied to the premix which initiates polymerisation to form a gel. The gel blocks the dentinal tubules and prevents fluid movement within the dentinal tubules. The result is a prevention or reduction of sensitivity or pain. Furthermore, the gel (a hydrogel) can swell in the presence of moisture in the mouth, causing the gel to tighten in the tubules, and thus is further prevented from falling out. Hence, the formulation of the invention has long term effectiveness compared with prior art formulations.

Accordingly, the invention is also directed to a method of preventing or reducing sensitivity or pain in at least one tooth, which method comprises applying to said tooth a polymer premix of the invention and curing said premix by application of light.

There is further provided according to the invention the use of at least one multifunctional polymer and/or at least one monomer, together with a light sensitive polymerisation initiator, for the preparation of a formulation for desensitising a tooth.

As employed above and throughout this disclosure (including the claims), the following terms, unless otherwise indicated, shall be understood to have the following meanings:

"Comprises/comprising" and grammatical variations thereof are to be taken to specify the presence of stated features, integers, steps or components or groups thereof, but not to preclude the presence or addition of one or more other features, integers, steps. components or groups thereof.

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"Desensitising" is to be taken as meaning reducing sensitivity or pain.

"Cured/curing" and grammatical variations thereof refers to the polymerisation process whereby the desensitising polymer is formed.

DETAILED DESCRIPTION OF THE INVENTION

Typically, the multifunctional polymer used to prepare the formulation of the invention is a polycarboxylic acid polymer.

The monomer is preferably an acrylate or allyl derivative. Most preferably the monomer is selected from hydroxy ethylmethacrylate, glycol dimethacrylate, diallyloxyacetic acid, poly(ethylene glycol) dimethacrylate, 2-acrylamidoglycolic acid, acrylic acid, methacrylic acid, and itaconic acid.

The light sensitive polymerisation initiator is preferably a quinone derivative in combination with a quaternary amine derivative. Most preferably the quinone derivative is camphorquinone. The quaternary amine derivative may be selected from N,N,3,5-tetramethyl aniline, poly(ethyleneimine), N,N,N,N–tetraethyldiethylenetriamine, and N,N–diethylethylenediamine. Most preferably the quaternary amine is tetramethyl aniline. On application of light in the wavelength range 300 to 650nm to the premix, the light sensitive initiator initiates the polymerisation of the premix to form the desensitising polymer.

Usually, the formulation is prepared by dissolving the polymer(s) and/or monomer(s) and polymerisation initiator in water, together with a preservative (to improve shelf life). A typically used preservative is butylated hydroxy toluene, although other preservatives such as hydroquinone, and methyl hydroquinone may be used.

A preferred formulation of the invention comprises

Polycarboxylic acid polymer	about 1 to about 50% by weight
Hydroxy ethylmethacrylate	about 1 to about 50% by weight
Glycol dimethacrylate	about 1 to about 50% by weight
Water	about 1 to about 70% by weight
Camphorquinone	about 0.01 to about 5% by weight
Tetramethyl aniline	about 0.01 to about 5% by weight
Butylated hydroxy toluene	about 0.01 to about 5% by weight

An even more preferred formulation of the invention comprises

Polycarboxylic acid polymer	about 7.5% by weight

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Hydroxy ethylmethacrylate	about 74.5% by weight
Diallyloxyacetic acid, sodium salt	about 6% by weight
Water	about 12% by weight
Camphorquinone	about 0.2% by weight
Tetramethyl aniline	about 0.22% by weight
Butylated hydroxy toluene	about 0.05% by weight

The invention will now be described with reference to the following example, which is not intended to limit the scope of the invention.

EXAMPLE

Definitions

Gantrez AN119BF is an alternating copolymer of vinyl methyl ether and maleic anydride.

HEMA is 2-hydroxy ethyl methacrylate.

BHT is butylated hydroxy toluene.

The following composition was prepared:

Gantrez AN119BF	7.5 grams
Deionised water	12.0 grams
HEMA	74.5 grams
Diallyloxyacetic acid, sodium salt	6.0 grams
Camphorquinone	0.20 grams
BHT	0.05 grams
Tetramethyl aniline	0.22 grams

Method

The equipment requirements were as follows:

a) Balance weighing in grams and reading to two decimal places
b) Pasteur pipettes
c) Two clean 500ml beakers
d) Plastic spatula
e) Ultrasonic bath

A clean glass beaker was placed on the balance and the balance tared. To the glass beaker was added 7.5 grams of Gantrez AN119BF, 12.0 grams of deionised water, 74.5 grams of HEMA, and 6.0 grams of diallyloxyacetic acid sodium salt. The mixture was stirred with a plastic spatula and then the beaker

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covered with plastic film. Water was poured into the ultrasonic bath to a depth of about one centimeter, and then the beaker placed in the ultrasonic bath. The ultrasonic bath was turned on to agitate the contents of the beaker until the mixture became clear, and there were no gel particles.

In an orange light production area, 0.20 grams of camphorquinone, 0.05 grams of BHT, and 0.22 grams of tetramethyl aniline was weighed into a clean glass beaker. Then the solution containing the Gantrez AN119BF was added to this beaker. The beaker was covered with plastic film and agitated in the ultrasonic bath until all the camphorquinone and BHT had dissolved.

The resultant product (the "premix") was packaged, ready for delivery.

This premix can then be applied to a painful or sensitive tooth, or to exposed dentine. Naturally, the premix can also be applied to a tooth which has no pain, but in anticipation of pain, for example before a surgical procedure. Light is directed onto the area to which the premix is applied to cause polymerisation. The desensitising polymer so formed reduces or prevents pain.

DATED this 20th day of December 2002

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